

REMARKS

Claims 1-54 are pending in this application. Claims 1-54 are subject to restriction/election. Claims 1-19, 22-24, 44 and 47-54 have been elected. Claims 20, 21, 25-43, 45 and 46 are withdrawn from consideration. Claims 1-10, 13-19, 22-24, 44 and 47-54 have been rejected under 35 U.S.C. §102. Claims 11, 12, 44 and 47-50 have been rejected under 35 U.S.C. §103. The drawings have been objected to. Reconsideration and reexamination is respectfully requested.

Election/Restriction

Claims 1-54 are subject to restriction/election. Consistent with a telephone conversation between the Examiner and Ted Rittmaster on April 17, 2003, Applicant respectfully traverses the election requirement and elects to prosecute Claims 1-19, 22-24, 44 and 47-54. Applicant reserves the right to file one or more divisional applications for claims 20, 21, 25-43, 45 and 46.

Drawings

The Examiner has objected to the drawings, stating that Claims 16 and 54 recite limitations not shown in the drawings. Applicant proposes new Figure 7, which shows a catheter 70 having an inner surface of the outer layer 72 which covers the outer surface of the barrier layer 74 only at the distal end of the catheter 70. No new matter has been added. With the Examiner's approval, Applicant will file a formal Figure 7 and amend the specification accordingly.

Rejection Under 35 U.S.C. §102

The Examiner has rejected Claims 1-10, 13-19, 22-24, 44 and 47-54 under 35 U.S.C. 102(b) as being anticipated by Lee et al., U.S. Patent #6,010,521. This rejection is respectfully traversed

Claims 1 and 53 recite a catheter having, *inter alia*, first and second materials wherein the second material has a permeability lower than polyethylene for at least one substance that could cause detrimental change in the properties or composition of the formulation. Claims 44 and 47 recite an implantable fusion pump system having, *inter alia*, a

catheter that includes, without limitation, the same feature. This feature is not disclosed or suggested in Lee.

Lee is directed toward a catheter formed in part from a multilayered member having a first layer fusion bonded to another catheter component. The first layer is bonded to the skirt of an inflatable balloon. The multilayered member also has a second layer adjacent the first layer having a *melting point* greater than the first layer so that the multilayered member of the catheter is not deformed when the other catheter component is fusion bonded to the first layer of the multilayered member. Lee does not disclose or suggest a catheter having first and second materials wherein the second material has a permeability lower than polyethylene for at least one substance that could cause detrimental change in the properties or composition of a formulation. In fact, the concept of permeability can not be found anywhere in the entire Lee patent.

Claim 54 recites a catheter having, *inter alia*, an outer layer and a barrier layer wherein the inner surface of the outer layer covers the outer surface of the barrier layer only at the distal end of the catheter. This feature is not disclosed or suggested in Lee.

Lee discloses a catheter where the inner layer and outer layer are coincident with one another over the length of the catheter. In some embodiments of the Lee catheter, the outer layer extends beyond the distal end of the inner layer to form a non-traumatic distal tip. There is no disclosure or suggestion in Lee of a catheter where the inner surface of the outer layer covers the outer surface of the barrier layer only at the distal end of the catheter.

Accordingly, there are limitations in independent Claims 1, 44, 47, 53 and 54 not disclosed or suggested in Lee. Thus, Lee cannot anticipate these claims. Likewise, Lee cannot anticipate claims 2-10, 13-19 and 22-24, which depend directly or indirectly from Claim 1, and Claims 48-52, which depend directly or indirectly from Claim 47, for at least the same reasons as Claim 1. Applicant respectfully requests that the Examiner withdraw the rejection of Claims 1-10, 13-19, 22-24, 44 and 47-54.

Rejection Under 35 U.S.C. §102

The Examiner has rejected Claims 11 and 12 under 35 U.S.C. 103(a) as being unpatentable over Lee et al., U.S. Patent #6,010,521, in view of Bogert et al, U.S. Patent #6,096, 012. This rejection is respectfully traversed.

Claims 11 and 12 both depend from Claim 1 and add to Claim 1 that the second material is capillary glass and diamond, respectively. As stated above, Lee does not disclose or suggest all of the features recited in Claim 1, and, thus, by extension, Claims 11 and 12. Moreover, not all of the features of Claims 11 and 12 are disclosed or suggested in Bogert.

Bogert is directed toward a disposable, coated, unitarily constructed, plastic catheter and cannula structure in which the tip end forms a sharp needle point coated with a hard material to facilitate insertion into a patient. In Bogert, the catheter is designed such that the sharp-tipped portion can penetrate the skin of a patient with minimal force. Bogert does not disclose or suggest a catheter having first and second materials wherein the second material has a permeability lower than polyethylene for at least one substance that could cause detrimental change in the properties or composition of a formulation. In fact, as with Lee, the concept of permeability can not be found anywhere in the entire Bogert patent.

Thus, neither Lee nor Bogert disclose or suggest, individually or in combination, all of the limitations of Claims 11 and 12. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d at 1438 (Fed. Cir. 1991). Accordingly, the Examiner has not established a *prima facie* case of obviousness with respect to Claims 11 and 12. Applicant respectfully requests that the Examiner withdraw the rejection of Claims 11 and 12.

The Examiner has rejected Claims 44 and 47-50 under 35 U.S.C. 103(a) as being unpatentable over Lee et al., U.S. Patent #6,010,521, in view of Polaschegg et al, U.S. Patent #4,966,579. This rejection is respectfully traversed.

As stated above, Lee does not disclose or suggest all of the features recited in Claims 44 and 47 and, by extension, Claims 48-50, which depend either directly or indirectly from Claim 47. Moreover, not all of the features of Claims 44 and 47-50 are disclosed or suggested in Polaschegg.

Polaschegg is directed toward an apparatus for dosed, continuous, simultaneous infusion of several solutions or medicaments which are arranged in a plurality of containers or syringes. The Polaschegg device is a complex piece of machinery and does not delve into the intricacies of catheter design. Polaschegg does not disclose or suggest a catheter having first and second materials wherein the second material has a permeability lower than polyethylene for at least one substance that could cause detrimental change in the properties or composition of a formulation. In fact, as with Lee and Bogert, the concept of permeability can not be found anywhere in the entire Polaschegg patent.

Thus, neither Lee nor Polaschegg disclose or suggest, individually or in combination, all of the limitations of Claims 44 and 47-50. Accordingly, the Examiner has not established a *prima facie* case of obviousness with respect to Claims 44 and 47-50. Applicant respectfully requests that the Examiner withdraw the rejection of Claims 44 and 47-50.

The Examiner has rejected Claims 51 and 52 under 35 U.S.C. 103(a) as being unpatentable over Lee et al., U.S. Patent #6,010,521, in view of Polaschegg et al, U.S. Patent #4,966,579, and further in view of Bogert et al, U.S. Patent #6,096, 012. This rejection is respectfully traversed.

Claims 51 and 52 depend directly from Claim 47. As stated above, neither Lee, Polaschegg or Bogert, disclose or suggest, individually or in combination, all of the limitations of Claim 47 and, by extension, Claims 51 and 52. Accordingly, the Examiner has not established a *prima facie* case of obviousness with respect to Claims 51 and 52. Applicant respectfully requests that the Examiner withdraw the rejection of Claims 51 and 52.

In view of the foregoing, reexamination and reconsideration are respectfully requested. It is submitted that the claims of record are in condition for allowance.

Respectfully submitted,

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